



## Clinical trial results:

**A phase II, randomised, open-label study to evaluate the safety and immunogenicity of the adjuvanted pandemic H1N1 influenza candidate vaccine following a 0-28 day or 0-4 month vaccination schedule in subjects aged 8 to 12 weeks.**

### Summary

EudraCT number	2009-015174-35
Trial protocol	NO
Global end of trial date	25 November 2010

### Results information

Result version number	v2 (current)
This version publication date	14 July 2021
First version publication date	13 June 2015
Version creation reason	<ul style="list-style-type: none"><li>• Correction of full data set</li></ul> Results have been amended to account for consistency with other registries.

### Trial information

#### Trial identification

Sponsor protocol code	113629
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01003418
WHO universal trial number (UTN)	-

Notes:

### Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium,
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com

Notes:

### Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	25 November 2010
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	25 November 2010
Was the trial ended prematurely?	Yes

Notes:

## General information about the trial

Main objective of the trial:

To evaluate the safety and reactogenicity of the H1N1 candidate vaccine in terms of solicited local and general symptoms, unsolicited adverse events (AEs) and serious adverse events (SAEs) two weeks post Dose 1.

Protection of trial subjects:

The vaccinees were observed closely for at least 30 minutes, with appropriate medical treatment readily available in case of anaphylaxis following the administration of vaccines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 November 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Norway: 8
Worldwide total number of subjects	8
EEA total number of subjects	8

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	8
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

Only 8 subjects were enrolled in the study as the study was prematurely terminated for logistic reasons, not related to safety or efficacy of the vaccine

### Pre-assignment

Screening details:

Subjects who were enrolled completed the study but the lack of data due to the small enrollment number prevented any statistical analyses to be performed. No statistical analyses were performed as per planned in the protocol. All study results summarized below are based solely on individual data listings generated.

### Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Flu A Group

Arm description:

Subjects received 2 primary doses of H1N1 vaccine, according to a 0-28 day schedule. Subjects also received routine infant immunisation (DTPa-IPV/Hib) and 7Pn vaccine at Day 14, Month 3 and Month 10.

Arm type	Experimental
Investigational medicinal product name	Pandemrix™
Investigational medicinal product code	GSK2340272A
Other name	A/California/7/2009 (H1N1)v-like vaccine adjuvanted with AS03, Split virion, inactivated A/California/7/2009 (H1N1)v-like
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 primary doses of H1N1 vaccine administered intramuscularly in the anterolateral region of the left thigh at Day 0 and right thigh at Day 28.

Investigational medicinal product name	Infanrix™ -IPV+HIB
Investigational medicinal product code	
Other name	DTPa-IPV/Hib
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses administered intramuscularly at Day 14, Month 3 and Month 10 in anterolateral region of right thigh.

Investigational medicinal product name	Prevenar™
Investigational medicinal product code	
Other name	7-valent pneumococcal conjugate vaccine
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses administered intramuscularly in the anterolateral region of left thigh at at Day 14, Month 3 and Month 10.

<b>Arm title</b>	Flu B Group
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**Arm description:**

Subjects received 2 primary doses of H1N1 vaccine, according to a 0-4 month schedule. Subjects also received routine infant immunisation (DTPa-IPV/Hib) and 7Pn vaccine at Day 14, Month 3 and Month 10.

Arm type	Experimental
Investigational medicinal product name	Pandemrix™
Investigational medicinal product code	GSK2340272A
Other name	A/California/7/2009 (H1N1)v-like vaccine adjuvanted with AS03, Split virion, inactivated A/California/7/2009 (H1N1)v-like
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

**Dosage and administration details:**

2 primary doses of H1N1 vaccine administered intramuscularly in the anterolateral region of the left thigh at Day 0 and right thigh at Month 4.

Investigational medicinal product name	Infanrix™ -IPV+HIB
Investigational medicinal product code	
Other name	DTPa-IPV/Hib
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

**Dosage and administration details:**

3 doses administered intramuscularly at Day 14, Month 3 and Month 10 in anterolateral region of right thigh.

Investigational medicinal product name	Prevenar™
Investigational medicinal product code	
Other name	7-valent pneumococcal conjugate vaccine
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

**Dosage and administration details:**

3 doses administered intramuscularly in the anterolateral region of left thigh at at Day 14, Month 3 and Month 10.

<b>Number of subjects in period 1</b>	Flu A Group	Flu B Group
Started	5	3
Completed	5	3

## Baseline characteristics

### Reporting groups

Reporting group title	Flu A Group
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Reporting group description:

Subjects received 2 primary doses of H1N1 vaccine, according to a 0-28 day schedule. Subjects also received routine infant immunisation (DTPa-IPV/Hib) and 7Pn vaccine at Day 14, Month 3 and Month 10.

Reporting group title	Flu B Group
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Reporting group description:

Subjects received 2 primary doses of H1N1 vaccine, according to a 0-4 month schedule. Subjects also received routine infant immunisation (DTPa-IPV/Hib) and 7Pn vaccine at Day 14, Month 3 and Month 10.

Reporting group values	Flu A Group	Flu B Group	Total
Number of subjects	5	3	8
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Standard deviation data was not available.			
Units: weeks			
arithmetic mean	9	8	
full range (min-max)	7 to 10	7 to 9	-
Gender categorical			
Units: Subjects			
Female	4	2	6
Male	1	1	2

## End points

### End points reporting groups

Reporting group title	Flu A Group
Reporting group description:	
Subjects received 2 primary doses of H1N1 vaccine, according to a 0-28 day schedule. Subjects also received routine infant immunisation (DTPa-IPV/Hib) and 7Pn vaccine at Day 14, Month 3 and Month 10.	
Reporting group title	Flu B Group
Reporting group description:	
Subjects received 2 primary doses of H1N1 vaccine, according to a 0-4 month schedule. Subjects also received routine infant immunisation (DTPa-IPV/Hib) and 7Pn vaccine at Day 14, Month 3 and Month 10.	

### Primary: Number of subjects with any, grade 3 and related unsolicited adverse events (AEs).

End point title	Number of subjects with any, grade 3 and related unsolicited adverse events (AEs). <sup>[1]</sup>
End point description:	
An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities/crying that cannot be comforted. Related = AE assessed by the investigator as related to the vaccination.	
End point type	Primary
End point timeframe:	
During the 2 weeks post-Dose 1 (Day 0-13)	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Flu A Group	Flu B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	3		
Units: Number				
Any AE(s)	2	2		
Grade 3 AE(s)	0	0		
Related AE(s)	0	0		

### Statistical analyses

No statistical analyses for this end point

### Primary: Number of Subjects With Any Solicited Local or General Symptoms

End point title	Number of Subjects With Any Solicited Local or General Symptoms <sup>[2]</sup>
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End point description:

Assessed solicited local symptoms were pain, redness and swelling. Assessed solicited general symptoms were drowsiness, fever, irritability and loss of appetite.

End point type Primary

End point timeframe:

During the 7-days post-Dose 1 period (Days 0-6)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Flu A Group	Flu B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	3		
Units: Subjects				
Pain	2	0		
Redness	2	0		
Swelling	2	0		
Drowsiness	3	1		
Fever	1	0		
Irritability	3	1		
Loss of appetite	0	1		

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Subjects With Any Solicited Local or General Symptoms

End point title Number of Subjects With Any Solicited Local or General Symptoms<sup>[3]</sup>

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Assessed solicited general symptoms were drowsiness, fever, irritability and loss of appetite.

End point type Primary

End point timeframe:

During the 7-days post-Dose 2 period (Days 28 + 7 days for Group 1; Month 4 + 7 days for Group 2)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Flu A Group	Flu B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	3		
Units: subjects				
Pain	3	0		
Redness	1	1		
Swelling	2	3		
Drowsiness	5	3		

Fever	3	2		
Irritability	3	2		
loss of appetite	2	1		

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of subjects with Serious Adverse Events (SAEs)

End point title	Number of subjects with Serious Adverse Events (SAEs) <sup>[4]</sup>
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End point description:

SAEs assessed included medical occurrences that resulted in death, were life threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity.

End point type	Primary
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End point timeframe:

During the 2-weeks post-Dose 1 period (Days 0-13)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Flu A Group	Flu B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	3		
Units: subjects	0	0		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with any, grade 3 and related unsolicited AEs

End point title	Number of subjects with any, grade 3 and related unsolicited AEs
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End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any AE reported in addition to those solicited during the clinical study. Also any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms will be reported as an unsolicited AE.

Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities/crying that cannot be comforted. Related = AE assessed by the investigator as related to the vaccination.

End point type	Secondary
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End point timeframe:

During the 28-day (Days 0-27) follow-up period after each study vaccine administration.



<b>End point values</b>	Flu A Group	Flu B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	3		
Units: Subjects				
Any AE(s)	3	2		
Grade 3 AE(s)	0	0		
Related AE(s)	0	0		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with serious adverse events (SAEs).

End point title	Number of subjects with serious adverse events (SAEs).
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End point description:

SAEs assessed included medical occurrences that resulted in death, were life threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity. Results about SAEs were based on individual listings.

End point type	Secondary
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End point timeframe:

During the entire study period (Day 0 - Month 11)

<b>End point values</b>	Flu A Group	Flu B Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	3		
Units: Subjects				
Any SAE(s)	0	0		

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms: Within 7 days (Day 0-6) follow up period after each study vaccination. Unsolicited AEs: Within 28-day follow-up period after each H1N1 vaccination. SAEs: Throughout the entire study (Day 0 to Month 11).

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	13.1

### Reporting groups

Reporting group title	Flu A Group
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Reporting group description:

Subjects received 2 primary doses of H1N1 vaccine, according to a 0-28 day schedule. Subjects also received routine infant immunisation (DTPa-IPV/Hib) and 7Pn vaccine at Day 14, Month 3 and Month 10.

Reporting group title	Flu B Group
-----------------------	-------------

Reporting group description:

Subjects received 2 primary doses of H1N1 vaccine, according to a 0-4 month schedule. Subjects also received routine infant immunisation (DTPa-IPV/Hib) and 7Pn vaccine at Day 14, Month 3 and Month 10.

Serious adverse events	Flu A Group	Flu B Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Flu A Group	Flu B Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	3 / 3 (100.00%)	
General disorders and administration site conditions			
Pain			
subjects affected / exposed	4 / 5 (80.00%)	0 / 3 (0.00%)	
occurrences (all)	4	0	
Redness			
subjects affected / exposed	2 / 5 (40.00%)	1 / 3 (33.33%)	
occurrences (all)	2	1	
Swelling			

subjects affected / exposed	2 / 5 (40.00%)	3 / 3 (100.00%)	
occurrences (all)	2	3	
Drowsiness			
subjects affected / exposed	5 / 5 (100.00%)	3 / 3 (100.00%)	
occurrences (all)	5	3	
Fever			
subjects affected / exposed	4 / 5 (80.00%)	2 / 3 (66.67%)	
occurrences (all)	4	2	
Irritability			
subjects affected / exposed	4 / 5 (80.00%)	3 / 3 (100.00%)	
occurrences (all)	4	3	
Loss of appetite			
subjects affected / exposed	4 / 5 (80.00%)	3 / 3 (100.00%)	
occurrences (all)	4	3	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 5 (20.00%)	1 / 3 (33.33%)	
occurrences (all)	1	1	
Tracheal inflammation			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 5 (20.00%)	1 / 3 (33.33%)	
occurrences (all)	1	2	
Conjunctivitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	
occurrences (all)	1	0	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 December 2009	On request of Paediatric Committee (PDCO)/Committee for Medicinal Products for Human Use (CHMP), reporting of vaccine effectiveness and vaccine failure were incorporated. One telephone contact per group was added after the second dose to monitor fever, based on previous paediatric study results.

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
25 November 2010	The study was terminated prematurely for logistic reasons not related to safety or efficacy of the vaccine; only eight subjects were enrolled in the study.	-

Notes:

### Limitations and caveats

None reported